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| 10/789,526 | 02/26/2004 | Kenneth W. Dobie | BIOL0002US | 9932 |

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| EXAMINER |
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EPPS FORD, JANET L

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1633

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06/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/789,526

Applicant(s)

DOBIE, KENNETH

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9,13,20-23,46,47 and 50-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,13,20-23,46,47 and 50-68 is/are rejected.
- 7) ☒ Claim(s) 7 and 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Claims 1, 3-7, 9, 13, 20-23, 46-47, 50-57, and new claims 58-68 are pending for examination.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

3. The rejection of claim 1, 3-6, 8, 10-13, 20-23, and 46-49 under 35 U.S.C. 102(e) as being anticipated by Dobie et al. (US Patent Application 2003-232438), is withdrawn in response to Applicant's amendment filed 2-27-07.
4. The rejection of claims 3-7, 9, 11-13, and 20-23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's amendment filed 2-27-07.
5. The rejection of claims 50-57 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in response to Applicant's amendment filed 2-27-07.

Double Patenting

6. Claims 1, 3-6, 13, 20-23, 46-47, 50-57 remain provisionally rejected, and new claims 58-68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15, 17-23 of copending Application No. 10/927,466 in view of Dobie et al., for the reasons of record.
7. Applicant's arguments filed 2-27-07 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that,

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consistent with MPEP § 804, Applicants respectfully requested that the "remaining provisional double patenting rejection be withdrawn and the instant Application be allowed to issue." However, contrary to Applicant's assertions, the instant provisional double patenting rejection is not the only remaining rejection of record in the instant application, see the following new grounds of rejection set forth below.

8. Claim 58 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 13. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 1, 4-6, 20, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Olek et al. (WO 2001077384 A2 (German)); Passages cited as set forth in English translation of this document US 2004023279).

Olek et al. discloses the sequence:

<210> SEQ ID NO 257516

<211> LENGTH: 13

<212> TYPE: DNA

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<213> ORGANISM: Artificial Sequence

<220> FEATURE:

<223> OTHER INFORMATION: Oligonucleotide for detection of SNP

TSC0062661

<400> SEQUENCE: 257516

Ttctttccattc

The underlined nucleotide sequence set forth above represents a 12 consecutive nucleobase portion of SEQ ID NO: 19 of the instant application. SEQ ID NO: 257516 of Olek et al. is at least 90% complementary to SEQ ID NO: 4 of the instant application. Moreover, the nucleic acid based compounds of Olek et al. are oligonucleotides or peptide nucleic acid oligomers and are useful in methods for the detection of cytosine methylation and single nucleotide polymorphisms.

11. Claim 63 is rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al. (WO 99/65928A2).

Roberts et al. discloses SEQ ID NO: 630 (see page 75), which is an oligonucleotide of 10 nucleobases in length, wherein said oligonucleotide is 100% complementary to SEQ ID NO: 4, and wherein said oligonucleotide consists of a 10 consecutive nucleobase portion of SEQ ID NO: 19 (nucleobases 1-10) of the instant application. The invention of Roberts et al. also encompasses wherein the oligonucleotide sequence disclosed on page 75 of the reference can be used to design an antisense RNA to these sequences or to their complements, see the following:

In addition to the sequences shown in Tables 1 and 2, this invention also provides the anti-sense polynucleotide stand, e.g. antisense RNA to these

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sequences or their complements. One can synthesize an antisense RNA based on the sequences provided in the Tables using any methods available in the art, (see bridging paragraph of pages 19-20).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1, and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olek et al. in view of Bennett et al. (US Patent No. 5,968, 748).

The scope of the instant claims encompass a compound according to claim 1 further comprising at least one phosphorothioate modified internucleoside linkage, 5-methylcytosine nucleobase, modified sugar, or combination thereof, wherein the modified sugar is a 2'-O(2-methoxyethyl).

The teaching of Olek et al. set forth above, is incorporated here. However, Olek et al. does not teach oligonucleotide compositions comprising phosphorothioate internucleoside modifications, 5-methylcytosine modifications, or 2'-O(2-methylethyl) sugar modifications.

Bennett et al. teach the modification of antisense oligonucleotides with at least one phosphorothioate modified internucleoside linkage, a 5-methylcytosine nucleobase, and a modified sugar, or combination thereof, wherein the modified sugar is a 2'-O(2-methoxyethyl) (col. 7, lines 1 and 60-62). Bennett et al. teach

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that such modified or substituted oligonucleotides are often preferred over native forms because of desirable properties such as, for example, enhanced cellular uptake, enhanced binding to target and increased stability in the presence of nucleases (col. 6, lines 58-62).

It would have been obvious to the ordinary skilled artisan at the time of the instant invention to modify the oligonucleotides of Olek et al. with at least one phosphorothioate internucleoside linkage, 5-methylcytosine modifications, and at least one sugar according to the present invention. One of ordinary skill in the art seeking to design oligonucleotides comprising an increased half-life, and increased effective concentration, would have been motivated to modify the oligonucleotides of Olek et al. to comprise the modifications of Bennett et al., since these modifications increase nuclease resistance, and increase the binding affinity of the oligonucleotide for its complementary sequence

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 46-47, 60, and 64-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 and those claims dependent therefrom, claims 47, 60, and 64-68, recite the limitation "an antisense oligonucleotide comprising *a nucleobase sequence of SEQ ID NO: 19.*" The scope of the phrase "a nucleobase sequence of SEQ IDNO: 19," as recited in the context of this claim is vague and indefinite

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since it lacks sufficient antecedent basis in claim 1. Claim 1 is limited to wherein the claimed compound comprises "an at least 8 consecutive nucleobase portion of SEQ ID NO: 19." The scope of dependent claim 46, is broader in scope than independent claim 1, therefore claim 46 also fails to further limit claim 1.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner
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JLE